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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/242,657	02/19/1999	PETER RUHDAL JENSEN	55411.000002	1335

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HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

EXAMINER

MCGILLEM, LAURA L

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/242,657	Applicant(s) JENSEN ET AL.	
	Examiner Laura McGillem	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-11,13-18,21-23,25 and 27 is/are pending in the application.
- 4a) Of the above claim(s) 1-15,21,23,25 and 27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 and 22 is/are allowed.
- 6) ☒ Claim(s) 17-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt of an After Final Amendment, filed 11/29/05 is acknowledged.

Applicants have cancelled claims 1-15, 21, 23, 25 and 27 and amended claims 16 and 18. Applicants submit that claims 16-18 and 22 are in condition for allowance.

In the Office Action mailed 6/29/05, claims 16-17 and 22 were indicated as allowable. However, claim 17 was inadvertently and mistakenly indicated as allowable. Claim 17 has been previously rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement regarding recitation of the phrase "each step changing the promoter activity by 50%-100%".

Applicants submit that claim 18 is in condition for allowance; however, claim 18 has been previously rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement regarding recitation of the phrase "each step changing the activity by 50%-100%". Notation of the rejection of claim 18 was inadvertently excluded from the Office Action mailed 6/29/05.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement for a genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed invention. The instant claims are drawn to a method wherein a plurality of promoter sequences is selected from the set of promoter sequences, said plurality of promoter sequences covering, in said selected microorganisms, a range of promoter activities for said gene, in steps, each step changing the promoter activity by 50-100%, and a method of controlling the expression of at least one gene product comprising changing the expression level of at least one gene comprising selecting a subset of promoter sequences suitable for optimizing the gene expression in a selected microorganism, sequences covering a range of promoter activities for the gene in small steps each step changing the activity by 50-100%.

The claimed promoters can be derived from any source to drive expression of any gene in any microorganism. The set of promoters must drive expression of an operably linked gene to a particular range of any possible range of promoter activities.

Functionally, the set of promoters must cover the range of expression in steps of 50-100%. Thus, the rejected claims encompass an enormous genus of promoter sets that must meet very specific functional limitations (i.e. expression of a gene in a microorganism, in steps of 50-100% change in promoter activity levels). If one stipulates a single range of promoter activity for the claimed promoter set as from 1-100 units/hour, one can cover the range in steps of -25 units/hour, -10 units/hour, -2 units/hour, etc. Thus, for every range of promoter activity, one can traverse the range in steps of 50-100% changes in activity in many different ways. Each of these different ways of traversing a given range of activity is likely to involve a series of different promoter constructs, each set possessing a different collection of promoters having different changes in the promoter sequence/structure.

There remains no structural/functional basis for one of skill in the art to envision such a broad range of promoter sets that retain the conserved sequences and satisfy the functional limitations of the claim with regard to step-wise increments in promoter activity among the members of the promoter set for the incredibly broad genus of such promoter sets. Therefore, one of skill in the art would not have been able to envision a representative number of specific promoter sets to describe the broad genus of promoter sets encompassed by the rejected claims. One of skill in the art would thus have reasonably concluded applicants were not in possession of the claimed invention.

Conclusion

Claims 16 and 22 are allowable.

The rejection of claims 17 and 18 are not new grounds of rejection since the rejections were made in a previous office action and are being reinstated here.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura McGillem, PhD
12/15/2005


DAVID GUZO
PRIMARY EXAMINER